UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Date: April 24, 2002

MEMORANDUM

SUBJECT: REVISION OF EXPOSURE ASSESSMENT FOR PLANTING OF SEED TREATED WITH LINDANE

FROM David Jaquith
Reregistration Action Branch 4
Health Effect Division (7509C)

TO: Becky Daiss
Reregistration Branch 4
Health Effect Division (7509C)

THRU Susan Hummel, Senior Scientist
Reregistration Branch 4
Health Effects Division (7509C)

Please find attached the occupational and residential exposure assessment for lindane

DP BARCODE D282418

Pesticide Chemical Codes: 009001

EPA Reg Nos:

EPA MRID Nos.: 42251901

PHED: No

## 1.0 INTRODUCTION

In March 2001 HED provided an exposure/risk assessment for seed treatment use of lindane (1). The document included on-farm treatments (using wheat as the typical treatment), planting the treated seed, and commercial seed treatment facilities. The treatment of seeds using on farm technology has not changed. The assessment of exposure during planting was derived from PHED V1.1 using the assumption that exposure from planting treated seed would be similar to that received from application of granular formulations of pesticides. Since that time HED has received a study actually measuring exposure during planting. The seed planting exposure assessment has been reviewed by HED personnel. The results and review of this study are presented in Appendix A.

## 2.0 CONCLUSIONS

HED has reevaluated the estimates of exposure and risk from planting of wheat and canola seed with lindane using a study specifically addressing this scenario rather than using PHED as a model for planting seeds. Using an oral NOAEL of 1.2 mg/kg/day to assess dermal risk and an inhalation NOAEL of 0.13 mg/kg/day the MOEs are :

| Estimation of Dermal and Respiratory Exposures or Risksof Workers Planting Wheat and Canola Seed Treated with Lindane | | | | |
|---|---|---|---|---|
| | Dermal Exposure (mg/kg/day) | Respiratory Exposure (mg/kg/day) | MOE | |
| | | | Derma 1 | Respiratory |
| Wheat | 0.0013 | 0.00011 | 920 | 1200 |
| Canola | 0.0015 | 0.00013 | 800 | 1000 |

Examination of the data from the revised assessment, derived from a planting study (not included in PHED) and the previous assessment from PHED indicates that there are a large number of non detect samples in both of the data sets. Since the original PHED-derived estimates, which separated loading from planting showed large numbers of non detects for the planting function, it is evident that the loading contributes the majority of the exposure and that the actual planting task contributes relatively little to the total exposure.

## 3.0 CALCULATION OF EXPOSURES

In order to estimate the exposures of workers planting seed treated with lindane a number of assumptions regarding amount of seed planted and other parameters were required.

1) It is assumed that 250 acres of wheat or canola can be planted in a day (2).

2) An average worker has a body weight of 60 kg (a change from the previous assessment due to changes in the toxicological parameters) for dermal assessment. A weight of 70 kg is used for inhalation assessments.

3) Wheat is planted at a rate of 120 lbs of seed per acre. Canola is planted at a rate of 4 lbs seed per acre.

4) The application rate of lindane on wheat seed is 0.68 oz/cwt (0.043 lb/cwt). For canola the rate is 23.3 oz/cwt (1.5 lb ai/cwt). See Appendix B.

5) The dermal absorption of lindane is 10 percent (1).

**3.1 Exposure Assessment for Wheat**

Amount of lindane handled per day:

Lbs ai/day = 250 A/day x 120 lb seed/A x 0.043 lb ai/100 lbs seed = 12.9 lb ai/day

The resulting dermal exposure using arithmetic mean values from Appendix A is:

Dermal Exposure (mg/kg/day) = 0.0597 mg/lb ai x 12.9 lb ai/day x 0.1 (abs) ÷ 60 kg bw

= 0.0013 mg/kg/day

The resulting dermal MOE using a NOAEL of 1.2 mg/kg/day is:

MOE = 1.2 mg/kg/day/0.0013 mg/kg/day = 920

The respiratory exposure is:

Respiratory Exposure (mg/kg/day) = 12.9 lb ai/day x 0.0006 mg/lb ai ÷ 70 kg

= 0.00011 mg/kg/day

The resulting respiratory MOE using a NOAEL of 0.13 mg/kg/day is:

MOE = 0.13 mg/kg/day/0.00011 mg/kg/day = 1200

**3.1 Exposure Assessment for Canola**

Amount of lindane handled per day:

Lbs ai/day = 250 A/day x 4 lb seed/A x 1.5 lb ai/100 lbs seed = 15 lb ai/day

The resulting dermal exposure using arithmetic mean values from Appendix A is:

Dermal Exposure (mg/kg/day) = 0.0597 mg/lb ai x 15 lb ai/day x 0.1 (abs) ÷ 60 kg bw

= 0.0015 mg/kg/day

The resulting dermal MOE using a NOAEL of 1.2 mg/kg/day is:

MOE = 1.2 mg/kg/day/0.0015 mg/kg/day = 800

The respiratory exposure is:

Respiratory Exposure (mg/kg/day) = 15 lb ai/day x 0.0006 mg/lb ai ÷ 70 kg

= 0.00013 mg/kg/day

The resulting respiratory MOE using a NOAEL of 0.13 mg/kg/day is:

MOE = 0.13 mg/kg/day/0.00013 mg/kg/day = 1000

REFERENCES

1) Memorandum from D. Jaquith (RRB4) to S. Shallal (RRB4) titled "OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT AND RECOMMENDATIONS FOR THE RE REGISTRATION ELIGIBILITY DECISION DOCUMENT FOR LINDANE", dated March 16, 2001.

2) Memorandum from S. Tadayon (CEB) to A. Khasawinah (RRB4) titled "OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT AND RECOMMENDATIONS FOR THE RE REGISTRATION ELIGIBILITY DECISION DOCUMENT FOR IMAZALIL" dated April 15, 2,000.

cc: Lindane file (009001)
R. Kent (RRB4/7509C)
Correspondence file
D. Jaquith (7509C)

APPENDIX A.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 03, 2002

Memorandum

SUBJECT: Exposures of Workers to Isofenphos During Planting of Oftanol-Treated Canola

FROM: Seyed Tadayon, Chemist
Chemistry Exposure Branch
Health Effect Division (7509C)

TO: Jeff Evans, Biologist
Chemistry Exposure Branch
Health Effect Division (7509C)

DP Barcode: D281351

EPA MRID No: 42251901

Attached is a review of the applicator exposure during planting of treated seed with Oftanol® which was submitted by Mobay Inc. This review was completed by Versar, Inc. on February 15, 2002, under supervision of HED. It has undergone secondary review in the HED and has been revised to reflect Agency policies.

**Executive Summary**

Oftanol® Technical is an insecticide incorporated into a seed-coating material that forms a hard, dry, shell-like layer on the outside of the canola seed. The purpose of this study was to quantify inhalation and dermal exposure to workers planting treated seed using the active ingredients isofenphos. The study met most of the criteria specified in Subdivision K (currently referred to as Series 875 .1100 and 875.1300 Group B).

## Summary

This study was conducted in Domain, Manitoba. Oftanol® Technical was applied to canola seeds prior to this study at a rate of 12 g ai (isofenphos) per kg of seed. Four workers were monitored four times, for a total of 16 replicates, as they opened and poured both the contents of the treated seed bags (25 kg) and fertilizer into their plant hoppers. The workers then drove a tractor, pulling the planter around the field planting between six and eight pounds of seed per acre. The workers used closed cab tractors with a ground speed ranging between 5 to 7 mph. Both seed and fertilizer traveled down a tube to the ground, where they were immediately covered with soil by a disc. Each replicate lasted an average of 3.22 hours and each worker handled an average of 4.33 lbs active ingredient per replicate

All workers wore long-sleeved shirts, coveralls, and chemical resistant gloves, in addition to their normal clothing. Air temperatures ranged from 69ºF to 82ºF and relative humidity ranged from 30 to 73%.

Exposure to the treated seed was quantified by the following methods:

a) Dermal exposure was estimated by 10 dermal patches. Dosimeters were attached to the worker's coverall at 10 locations: With this arrangement, the coveralls represented a single layer of normal clothing and the inner dosimeters collected the isofenphos that could reach the workers'skin if they were wearing only a single layer of clothing.

b) Exposure to the workers' hands was determined by the hand-rinse method.

c) Inhalation exposure was monitored by attaching a quartz microfiber (QMA) filters in polystyrene cassettes to the workers' lapels.

d) Cholinesterase activity was monitored by collecting blood samples.

Exposure values for both potential (based on exterior patches) and actual (based on interior patches) dermal exposures was calculated. The Registrant corrected all data for field fortification recoveries, including recoveries above 90%. For those values below the LOD, the Registrant used ½ the recovery corrected LOD value. Versar only corrected data for field fortification recoveries less <90% and reported non-detect values as ½ LOD.

Total potential dermal exposures ranged from 0.0095 to 1.2369 mg/lb ai handled. The primary body region contributors were the lower arm (0.1110 mg/lb ai handled) and the lower leg (0.0712 mg/lb ai handled). The overall average total potential dermal exposure was 0.3326 ± 0.3555 mg/lb ai handled. The actual dermal exposure estimates ranged from 0.0028 to 0.1053

mg/lb ai handled with an overall average actual dermal exposure of 0.0296 ± 0.0314 mg/lb ai handled. Total dermal exposure estimates included both actual dermal exposures and hand exposures and averaged 0.0597 ± 0.1001 mg/lb ai handled. Total exposure was calculated by taking the sum of all exposure routes (dermal-hands, dermal-body, and inhalation). The Registrant calculated a geometric mean total exposure of 0.15 mg/lb ai applied. Versar's calculated total exposure is presented in Table 8 and averaged 0.060 ± 0.101 mg/lb ai handled.

## Conclusions

Dermal and inhalation exposures were assessed during the planting of treated canola seed. The workers performed both loading of the treated seed into seed hoppers and planting of the seed. Table 1 provides a summary of the total exposure to isofenphos during loading and planting of treated seed, as calculated by Versar. Versar's calculated average total exposure was 0.060 ± 0.101 mg/lb-ai handled. The geometric mean total exposure, as calculated by the Registrant, to isofenphos during planting of treated canola seed was 0.15 mg/lb ai applied. The study author also reported total exposure in mg/replicate and assumed that a worker is able to complete three replicates per day. The study author estimated an average daily exposure of 1.9 mg, but noted that a worker would probably not routinely work what is equivalent to three replicates per day during the planting season so that actual daily exposure would likely be less than 1.9 mg/day.

Table 1:Summary of Total Exposure to Oftanol During Loading and Planting Treated Canola.

| Replicate | Exposure (mg/lb ai handled) | | | | |
|---|---|---|---|---|---|
| | Dermal-body | Dermal-hands | Dermal-Total | Inhalation | Inhalation + Dermal Total |
| 1 | 0.0731 | 0.0104 | 0.0835 | 0.0011 | 0.085 |
| 2 | 0.1053 | 0.0069 | 0.1122 | 0.0018 | 0.114 |
| 3 | 0.0033 | 0.0034 | 0.0067 | 0.0002 | 0.007 |
| 4 | 0.0053 | 0.0046 | 0.01 | 0.0002 | 0.01 |
| 5 | 0.0249 | 0.0046 | 0.0295 | | 0.029 |
| 6 | 0.016 | 0.0056 | 0.0216 | 0.0002 | 0.022 |
| 8 | 0.0028 | | 0.0028 | 0 | 0.003 |
| 9 | 0.0411 | 0.3333 | 0.3745 | 0.0024 | 0.377 |
| 11 | 0.0108 | 0.0068 | 0.0176 | 0.0004 | 0.018 |
| 13 | 0.058 | 0.0043 | 0.0623 | 0 | 0.062 |
| 14 | 0.0124 | 0.0051 | 0.0174 | 0 | 0.017 |
| 15 | 0.0199 | 0.0032 | 0.0231 | 0.0002 | 0.023 |
| 16 | 0.0117 | 0.0037 | 0.0153 | 0.0002 | 0.016 |
| Average | 0.0296 | 0.0327 | 0.0597 | 0.0006 | 0.06 |
| Standard Deviation | | | | | 0.101 |

Attachment

Versar Review Memo dated Febuary 15, 2002

**Reviewer: Kelly McAloon/Marit Espevik Date February 15, 2002**

**STUDY TYPE:** Applicator Passive Dosimetry Study Using Patch Dosimetry, Hand Washes, Inhalation Monitoring, and Cholinesterase Monitoring.

**TEST MATERIAL:** OFTANOL® Technical insecticide, a viscous liquid material formulation containing 90% isofenphos as the active ingredient.

**SYNONYMS:** 1-Methylethyl-2-[[ethoxy[(1-methylethyl)amino]phosphinothioyl]oxy]benzoate (CAS # 25311-71-1); Isofenphos (ISO-E, BSI); Isophenphos (ISO-F)

**CITATION:**

| | |
|---|---|
| Author: | V.C. Dean |
| Title: | *Exposures of Workers to Isofenphos During Planting of Oftanol-Treated Canola Seeds* |
| Report Date: | January 20, 1990 |
| Performing Organization: | Mobay Corporation<br>Corporate Occupational and Product Safety<br>Agricultural Chemicals Division<br>P.O. Box 4913, Hawthorn Rd.<br>Kansas City, MO 64120 |
| Identifying Codes: | MRID 422519-01; Report Number 99799; |

**SPONSOR:** Mobay Corporation
Agricultural Chemicals Division
Research & Development Department

**EXECUTIVE SUMMARY:**

The purpose of this study was to quantify inhalation and dermal exposure of workers handling canola seed treated with OFTANOL® Technical, containing 90% isofenphos as the active ingredient. The seeds had been treated with OFTANOL® Technical prior to this study and 25 kg bags of treated seed were provided for this exposure study. The study was conducted in Domain, Manitoba from May 16-23, 1989. Four workers were monitored four times, for a total of 16 replicates, as they loaded the treated seed into seed hoppers and drove tractors, planting between six and eight pounds of seed per acre. Each replicate lasted an average of 3.22 hours and each worker handled an average of 4.33 lbs active ingredient per replicate.

Dermal exposure was estimated by handwashes and by dermal patches attached to the inner and outer clothing of each worker. Total dermal exposure was calculated by adding the dermal exposure to the hand exposure values. Inhalation exposure was measured using a conventional industrial hygiene methodology. The Registrant provided exposure values expressed in mg/hr, mg/replicate, and mg/lb ai applied. Total dermal exposure to isofenphos, determined by the Registrant, ranged from 0.076 mg/lb ai applied to 0.42 mg/lb ai applied. The geometric mean total dermal exposure was estimated as 0.15 mg/lb ai applied. The geometric mean inhalation exposure to isofenphos was estimated as 0.0003 mg/lb ai applied. Total exposure to isofenphos ranged from 0.076 mg/lb ai applied to 0.43 mg/lb ai applied and the geometric mean was 0.15 mg/lb ai applied. The study author also reported an average daily total exposure of 1.9 mg/day, assuming that a worker is able to complete three replicates per day.

Versar calculated exposure estimates in mg/lb ai handled, as per EPA's request. Raw residue data were corrected using the field fortification recoveries. Versar only corrected for field recoveries less than 90%. Versar calculated a mean potential

inhalation exposure of 0.0006 ± 0.0008 mg/lb ai handled. The overall average dermal exposure and the average hand exposure, as calculated by Versar, were 0.0296 ± 0.0314 and 0.0327 ± 0.0947 mg/lb ai handled, respectively. Total dermal exposure was calculated as the sum of the overall dermal exposure and hand exposure and averaged 0.0597 ± 0.1001 mg/lb ai handled. Versar also calculated total exposure as the sum of all exposure routes. The average total exposure was estimated 0.060 ± 0.101 mg/lb ai handled.

The Study Report also included cholinesterase monitoring results. These results show that the isofenphos exposures to the workers were well within the acceptable limits. The greatest deviations observed were 7.7% in the plasma and 3.7 % in the erythrocytes. The study author attributed these deviations to natural variations.

The study met most of the Series 875.1100 and 875.1300 Guidelines. The major issues of concern were: (1) this study was performed at only one test site, (2) raw field data were corrected for all recoveries, even those greater than 90%, (3) concurrent laboratory fortification recoveries were not provided in the Study Report, (4) the limit of quantification was not provided for any media, only the limit of detection, (5) the analysis dates were not provided for any of the samples in this study in order to verify storage stability results, (6) individual field blank results were not provided in the Study Report, (7) there was only one field fortification level for air filter samples, (8) the Registrant used ½ the recovery corrected sample quantification limits for non-detect values, rather than ½ the method limit of detection for that media, (9) method validation recoveries were not provided for handwash samples, (10) information on the individuals who participated in this study was not provided, (11) the inhalation methodology was calibrated with an airflow of 1L/min instead of 2L/min, (12) the Registrant used the inhalation geometric mean for replicate 5 since no sample was collected, (13) the Registrant used values slightly different from the NAFTA recommended body region surface areas, and (14) the Registrant calculated face exposures from head exposures.

**COMPLIANCE:** A signed and dated Data Confidentiality statement was provided. The study sponsor waived claims of confidentiality within the scope of FIFRA Section 10(d) (1) (A), (B), or (C). The study sponsor stated that the EPA Good Laboratory Practice Standards (40 CFR part 160) did not apply to the study.

**GUIDELINE OR PROTOCOL FOLLOWED**: A study protocol was provided with the Study Report. OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A: 875.1100 (dermal exposure), and 875.1300 (inhalation exposure) were followed for the compliance review of this study.

## I. MATERIALS AND METHODS

### A. MATERIALS

#### 1. Test Material:

Formulation: OFTANOL® Technical insecticide contains 90% (by weight) of isofenphos as the active ingredient (ai). This product is a viscous liquid material that is used as a seed treatment.

| | |
|---|---|
| Lot/Batch # technical: | 8-00-5270A |
| Lot/Batch # formulation: | Not provided. |
| Purity in technical: | The OFTANOL® Technical was assayed during production at 91.8% isofenphos. |
| CAS #(s): | 25311-71-1 |
| Other Relevant Information: | EPA Registration number is 3125-326. |

#### 2. Relevance of Test Material to Proposed Formulation(s):

The product label was not provided for the test material used in this study. Versar was able to locate a product label with the same product name as the one used in this study.

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#### 3. Packaging:

The packaging of the test product was not reported in the study. All seed coating was performed prior to this study and 25 kg bags of treated seed were provided for this study.

## B. STUDY DESIGN

There were 3 deviations to the protocol: (1) in addition to the analyses of plasma and erythrocyte levels, whole blood levels were also evaluated. Mobay Corporation's cholinesterase analysis procedure includes whole blood and it was, therefore, routinely included in the analysis, (2) one blood sample was collected the morning after a worker completed his monitored work cycle rather than immediately afterwards, and (3) for replicate sampling, three of the sixteen replicates monitored were not included in the data evaluation. No adverse effects due to these deviations were reported in the Study Report.

### 1. Number and type of workers and sites:

Four individuals participated in the study at one test site, each serving as a subject four times, for a total of sixteen replicates. Each test subject was a private grower. The number of years of experience per worker was not provided. Each participant signed an informed consent form prior to the initiation of the study after being provided the proper information regarding the study, products being used, and proper precautions.

The seed treatment was performed on canola seed prior to this study in Nisku, Alberta, Canada, from January 17-19, 1989. This study took place in Domain, Manitoba where the treated canola seeds were planted from May 16-23, 1989.

### 2. Meteorology:

Air temperatures, relative humidity, and wind speed and direction were reported for the four sampling days. Air temperatures ranged from 69°F to 82°F and relative humidity ranged from 30 to 73%. Wind speed was reported as gusty for the first two sampling days, with wind speeds ranging from 10-30 mph. Wind speed on the remaining two sampling days ranged from 0-10 mph. Wind direction was reported as variable.

### 3. Replicates:

Each of the four workers were monitored for four replicates as they opened and poured both the contents of the seed bags and fertilizer into their plant hoppers. The workers then drove a tractor, pulling the planter around the field planting between six and eight pounds of seed per acre. Table 1 presents a summary of the hours worked and the lb ai handled for all of the replicates.

Table 1. Summary of Replicates

| Date | Replicates * | Worker ID | Hours Worked | lb ai handled |
|---|---|---|---|---|
| 37391 | 1 | A | 2.73 | 1.92 |
| 37391 | 2 | A | 2.25 | 2.88 |
| 37391 | 3 | B | 4.33 | 5.95 |
| 37391 | 4 | B | 3.08 | 4.32 |
| 37391 | 5 | C | 3.03 | 4.32 |
| 37391 | 6 | C | 3.08 | 3.6 |
| 37392 | 8 | D | 1.83 | 4.32 |
| 37392 | 9 | A | 4.75 | 5.76 |
| 37392 | 11 | B | 3.62 | 2.94 |
| 37393 | 13 | D | 2.87 | 4.62 |
| 37393 | 14 | D | 2.58 | 3.96 |
| 37398 | 15 | C | 4.62 | 6.24 |
| 37398 | 16 | C | 3.13 | 5.46 |

* Replicates 7, 10, and 12 not used.

**4. Protective clothing:**

All workers wore long-sleeved 65% polyester/35% cotton work shirts, 65% polyester/35% cotton coveralls, and chemical resistant (nitrile, Best No. 730) gloves, in addition to their normal clothing (denim trousers, cotton shirts, boots or tennis shoes, and baseball caps). The long-sleeved shirts, coveralls and caps were supplied by Mobay Corporation and served as attachment sites for dermal dosimeters. The gloves, also supplied by Mobay Corporation, were used only as protective equipment.

**5. Planting method:**

Worker A: Worker A used an International 310 Diskall pulled by a closed cab tractor at a ground speed of 7 mph. The worker opened the bags of treated seed and poured them into the seeder hopper. Fertilizer was also loaded into a hopper. Both seed and fertilizer dropped to the ground and were immediately covered with soil by a disc. This equipment arrangement provided for a 45 ft swath.

Worker B: Worker B used a Coop-Implements - G-100 Disker pulled by a John Deer 8630 close cab tractor at a ground speed of 5 mph. The worker cut the bags open with a pocket knife, stood on the back of the seeder and poured the 25 kg bag of treated seed into the trough of the seeder. Fertilizer was also poured into the seeder. Both seed and fertilizer traveled down a tube to the ground, where they were immediately covered with soil by a disc. This equipment arrangement provided for a 30 ft swath.

Worker C: Worker C used an Air System 1502 Concord seeder, pulled by a Steiger/Cougar 1000 closed cab tractor at a ground speed of 6 mph. The Concord Air tank is attached to an EZZE-On Cultivator. The worker loaded the bags of treated seed into the back of a fertilizer truck. The truck was driven to the field and poured into the hopper of the seeder. Fertilizer was conveyed from the truck by an auger to a hopper on the seeder. Both seed and fertilizer were conveyed by air up to the planter, where they were deposited into the soil. This equipment arrangement provided for a 36 ft swath.

Worker D: Worker D used a Chinook 1203, pulled by a Steiger CP 1360 closed cab tractor at a ground speed of 6 mph. The Chinook 1203 has two hoppers, one for seed and one for fertilizer. The worker opened the 25 kg bags of treated seed and poured them into the seed hopper of the Chinook 1203. Seed and fertilizer traveled from the hoppers through tubing to the ground and were deposited into the soil. This equipment arrangement provided for a 40 ft. swath.

**6. Application Rate:**

OFTANOL® Technical is an insecticide incorporated into a seed-coating material that forms a hard, dry, shell-like layer on the outside of the canola seed. According to the study author, the coated seeds are virtually dust-free, when applied in this manner. The insecticide protects newly sprouted canola plants against the flee beetle.

OFTANOL® Technical was applied to canola seeds prior to this study at a rate of 12 g ai (isofenphos) per kg of seed. All of the seed coating was done in Nisku, Alberta, Canada, from January 17-19, 1989. A product label was not provided in the Study Report. Versar was able to obtain a product label, but the label did not provide a recommended application rate.

Since OFTANOL® Technical is not registered in Canada, this study was conducted under Research Permit Sub. No. 89-007.

**7. <u>Exposure monitoring methodology:</u>**

Dermal dosimeters: Dermal exposure was estimated by 10 dermal patches. Dosimeter units consisted of a 3-inch by 3-inch 12-ply gauge surgical sponge enclosed in an aluminized paperboard holder. Dosimeters were attached to the worker's coverall at 10 locations: both upper arms, both palmar forearms three inches above the wrists, right chest just above the pocket, left back at the shoulder blade, the front of both thighs, and both shins. Each paperboard holder had a circular opening, 5.6 cm in diameter, which faced away from the body to allow isofenphos to collect on the gauze sponge. One dosimeter was also attached to the worker's cap just above the bill and a second set of dosimeters was attached to the worker's clothing inside the coveralls at the following locations: both upper arms, both palmar forearms, left chest, right back, both thighs, and both shins. With this arrangement, the coveralls represented a single layer of normal clothing and the inner dosimeters collected the isofenphos that could reach the workers' skin if they were wearing only a single layer of clothing.

Dosimeters were worn until the completion of the monitoring period, including maintenance, checking seed and fertilizer levels, and changing sites. At the end of the monitoring interval, the dosimeters were removed from the clothing and placed on a table. When all the dosimeters were removed, the gauze sponges were removed from their paperboard holders with tweezers and placed in labeled 1-ounce glass bottles which were capped with polyseal-lined screw caps and stored on dry ice.

Hand: Exposure to the workers' hands was determined by the hand-rinse method. At the end of the monitoring period, and at intermediate times when hands would normally be washed, the worker's hands were rinsed using the following procedure: 200 mL portion of absolute ethanol was placed into a 42-oz Whirl-Pak bag. The worker placed one hand into the bag and the bag was held tightly around the wrist. The hand and bag were shaken 50 times. The ethanol was stored in the plastic bag and used for subsequent washes during the monitoring period until the final wash. After the final wash, it was transferred into a 800 mL bottle for storage. Each hand was washed twice, for a total of four washed per replicate. After each of the four washes, the solution was transferred into a 800 mL bottle and vigorously shaken 50 times. An aliquot of the combined solution (left and right hand) was then transferred into a one-ounce labeled sample bottle and placed on dry ice. The remaining solution was discarded. On seven occasions, the outsides of the workers' gloves were washed by the same method to provide a comparison of the amounts of isofenphos residues on hands and gloves.

Inhalation: Inhalation exposure was monitored using a conventional industrial hygiene methodology. Quartz microfiber (QMA) filters in polystyrene cassettes were attached to the workers' lapels. Air was drawn through the filters at approximately 1 L/min by a portable, battery-powered pump (Gilian HFS 113A) attached to the workers' belt and connected to the filter cassette with PVC tubing. The filters removed particulates and aerosols containing isofenphos from the air during exposure sampling. When sampling was complete, the cassette was removed, capped, placed in a Whirl-Pak and stored on dry ice.

Cholinesterase: Blood samples were collected by venipuncture for determination of cholinesterase activity in the erythrocyte and plasma fractions. The puncture site was washed thoroughly with alcohol before sampling to sterilize and remove any isofenphos contamination that could affect the cholinesterase results. The following schedule was used: 1) Three pre-exposure samples were collected to establish the baseline value for each participant. They were collected during the week before planting began. Participants and Chemargro Ltd. technical personnel gave assurances that participants had not

worked with cholinesterase-inhibiting materials for a two-week period prior to the baseline sampling; and 2) one sample was collected at the end of each workday, when all work with isofenphos was completed. All samples were collected by a locally licensed nurse. They were shipped by overnight express to the Mobay Corporation Toxicology Laboratory in Stilwell, Kansas. The samples were analyzed the following morning, using an automated modified Ellman method. Results were communicated by telephone to the study site at mid-day on the day following sample collection.

All samples collected during mornings were stored in ice chests on dry ice for approximately four hours until field collection activities for the afternoon replicates were complete. All samples were then repacked on dry ice for shipping to the Mobay Corporation Analytical Laboratory in Kansas City, Missouri. At the analytical laboratory, the samples were stored in freezers at -7 degrees Celsius.

**8. Analytical Methodology:**

Extraction method(s):

Dermal Exposure Patches - 15 mL of ethanol was pipetted into sample vials and the vials were recapped. The sample vials were placed in a vertical position on a rotator and spun for 30 minutes to ensure complete absorption. Five mL of the sample solution was pipetted into a clean 15-mL vial and 0.5 mL of a 0.5% carbowax solution was added. The solvent was evaporated from the sample solution using a stream of dry nitrogen and a heating block at 43ºC. The sample residue was reconstituted by pipetting 5 mL of t-butyl methyl ether (MTBE) into the sample vial. The vial was capped with a polyseal and shaken for 30 seconds.

Handrinse Samples - The samples were shaken vigorously and then a portion was filtered using a LID/X filter. A portion of the filtered solution was immediately transferred into an autosampler vial and the vial was capped.

Air Filters- Filters were transferred to 0.5-ounce vials and 2.0 mL of MTBE was added. The vial was sealed with a polyseal lid and gently swirled to wet the filter thoroughly. The sample vial was placed on a rotator, the rotator wheel was put in a vertical position, and the vial was spun for 30 minutes to ensure complete desorption.

Detection method(s): See Table 2.

Table 2. Summary of GC Chromatographic and HPLC Conditions

| Media | Air Filters | Dermal pads | Hand Rinses |
|---|---|---|---|
| Instrument | Varian Model 3400 | Varian Model 3400 | Shimadzu CR-3A /Varian 4270 |
| Column | J&W, 0.541mm i.d. x 15m length DB-Wax fused-silica capillary column with a 1.0$\mu$m film thickness | J&W, 0.541mm i.d. x 15m length DB-Wax fused-silica capillary column with a 1.0$\mu$m film thickness | DuPont Zorbax C-8 column, 4.6mm i.d. x 25 cm length with a 0.45$\mu$m pore size |
| Detector | Nitrogen/phosphorous detector | Nitrogen/phosphorous detector | |
| Temperatures | Column: Initial: 100°C<br>Final: 185°<br>Injector: 250°C<br>Detector: 300°C | Column: Initital: 100°C<br>Final: 185°<br>Injector: 250°C<br>Detector: 300°C | Column: Ambient |
| Injection Volume | 9 µL | 9 µL | 100 µL |
| Retention Time | Isofenphos: 12.3 min<br>Isofenphos oxygen analog: 13.5 min | Isofenphos: 11.6 min<br>Isofenphos oxygen analog: 12.7 min | Isofenphos: 10.5 min<br>Isofenphos oxygen analog: 3.8 min |
| Quantitative Range | 0.0025-0.05 ng/$\mu$L | 0.0025-0.05 ng/$\mu$L | 0.2-10 ng/$\mu$L |

Method validation: The limit of detection (LOD) for air filters, gauze pads, and handwash samples was approximately 5ng/sample, 38 ng/sample, and 40 $\mu$g/sample, respectively. For method validation, five air filter samples were fortified at the 0.2 $\mu$g level for both isofenphos and its oxygen analog. Fourteen dermal gauze samples were fortified at loadings of 1.0, 10, 100, and 1000 $\mu$g of isofenphos under field conditions. Handwash samples were fortified at loadings of 100 and 1000 $\mu$g using field samples. Method validation recoveries for the air filter samples averaged 109.0% ± 3.6% for isofenphos and 94.4% ± 7.3% for its oxygen analog. Recoveries for the dermal gauze pads averaged 96.9%±6% and 94.2%±3%, for the 1.0 and 1000 $\mu$g loadings respectively. Method validation recoveries for handwash samples were not reported in the Study Report.

Instrument performance and calibration: According to the Study Report, analytical calibration standard curve data were generated before and after each set of samples analyzed. Standard concentrations were chosen to bracket the sample concentrations. Only concentrations within the validated range for each media were used.

Quantification: Sample concentrations were calculated using the linear regression function of a chromatography software. Concentrations of isofenphos in the samples were determined directly from the standard curve.

**9. <u>Quality Control:</u>**

Lab Recovery: Laboratory recoveries were not reported in the Study Report.

Field blanks: Field blanks were collected for each media. All values were reported to be less than the LOD, except for 2 gauze pad samples (0.170 and 11.7 $\mu$g).

Field recovery: <u>Handwash Samples:</u> Duplicate handwash samples were fortified at 200 and 2000 $\mu$g levels each sampling

day at the site by spiking a 200 mL ethanol portion with isofenphos formulation solutions. The spiked solutions were transferred into separate polyethylene bags and shaken 50 times. A portion of each sample was transferred from the plastic bags into 1-oz bottles and the bottles were capped with polyseal lids to simulate the procedure for collecting field samples.

Air Filters: Seven replicate filter samples were prepared each day by spiking 37-mm, acetonitrile washed Whatman QM-A filters with isofenphos formulation solution at a loading of approximately 0.2 $\mu$g of isofenphos. The spiked filters were then placed in separate filter cassettes. Each filter was supported by a stainless steel screen. Each cassette was then sealed tight with a cellulose shrink band and the two open ends were capped. To simulate the collection of field samples, the caps of each cassette were removed immediately before sampling and each filter unit was connected to a sampling pump which had been calibrated to a sampling rate of 1.0 L per minute. In addition, two blank filters were prepared at the same time to determine potential interference or contamination problems.

Dermal samples: Seven replicate samples were generated at loading levels of approximately 1.0, 10, 100, and 1000 $\mu$g of isofenphos to simulate anticipated exposure levels for the outer gauze and 1.0, and 10 $\mu$g to simulate inner gauze pads. To spike the outer gauze pads, 0.5 mL of spiking solutions containing approx 2.0, 20, 200, and 2000 $\mu$g/mL of isofenphos was pipetted onto separate gauze pads. Once the gauze pads were spiked, the solvent was allowed to evaporate. The spiked pads were placed in direct sunlight and exposed to the environment for approximately the same duration as the field samples. The inner pads were spiked in the same manner, but were placed under coverall material and were not exposed to sunlight.

Field fortification recoveries for isofenphos are presented in Table 3.

Table 3. Field Fortification Recoveries for Isofenphos

| Sample Type | Fortification Level ($\mu$g) | Sampling Day | Average Fortification Recovery per Day (%) | Average Isofenphos Recovery per Level (%) | Overall Average (%) | Standard Deviation |
|---|---|---|---|---|---|---|
| Handwash samples | 200 | 1234 | 111.3<br>109.1<br>97.5<br>98.3 | 104.1 | 102.4 | 6.6 |
| | 2000 | 1234 | 108.1<br>103.4<br>98.2<br>92.8 | 100.6 | | |
| Filters | 0.2 | 1234 | 100.1<br>69.9<br>86.0<br>93.9 | 88.1 | 88.1 | 12.2 |
| Outer Gauze Pads | 1 | 1234 | 107.3<br>73.3<br>100.8<br>88.9 | 92.6 | 90.1 | 12.1 |
| | 10 | 1234 | 98.2<br>73.0<br>84.2<br>97.0 | 88.2 | | |
| | 100 | 1234 | 87.0<br>86.1<br>78.4<br>110.4 | 90.9 | | |
| | 1000 | 1234 | 82.7<br>89.8<br>85.4<br>96.2 | 88.6 | | |
| Inner Gauze Pads | 1 | 1234 | 112.7<br>78.2<br>84.8<br>116.3 | 98.5 | 96.3 | 17.1 |
| | 10 | 1234 | 92.9<br>75.8<br>92.8<br>114.6 | 94.1 | | |

Formulation: The test products used were not characterized for this study.

Storage Stability: The Study Report indicated that storage stability experiments were performed prior to the commencement of this study.

Air filters: Approximately 0.2 $\mu$g isofenphos and its oxygen analog were field spiked onto QM-A filters. Air

was pulled through the spiked filters at 1.0 L/min ± 5% for 3.5 hours. The samples were then shipped to the Environmental Analysis Laboratory in Kansas City and stored in the freezer at -7°C for up to 72 days. Average recoveries ranged from 91.9% ± 12 to 110% ± 24.

Gauze pads: A field study was conducted at Vero Beach, Florida, using isofenphos canola seed formulation to fortify gauze pads. Seven pads were fortified at 0.990 μg isofenphos and exposed to outdoor environmental conditions for 4.5 hours. The samples were shipped to the Environmental Analysis Laboratory in Kansas City and stored in the freezer for 40 days prior to analysis. The average total recovery from the gauze pad samples was 104% ± 2%. Three indoor sampling field studies were also conducted at a seed coating facility in Nisku, Alberta, Canada. Gauze pads were fortified with isofenphos canola seed formulation and exposed to the indoor environment of the seed coating facility for 8 hours. The samples were shipped to the Environmental Analysis Laboratory in Kansas City and stored for up to 159 days. Average recoveries ranged from 94.0% ± 1.7% to 118% ± 4%.

Hand Rinses: The study author reported an average storage recovery of 110% ± 5% for storing samples of isofenphos in absolute ethanol at a 100-μg loading for 117 days at -7°C. The study author also reported average recoveries for storing samples spiked with 203 or 2031 μg isofenphos at -7°C for 158 days of 112% ± 1% and 110% ± 3%, respectively.

**10. Relevancy of Study to Proposed Use:**

The study monitored workers performing their normal duties during planting of treated canola seed.

## II. RESULTS AND CALCULATIONS:

### A. EXPOSURE CALCULATIONS:

The study author provided exposure values expressed as mg/replicate, mg/hour, and mg/lb ai applied for both dermal and inhalation exposure. The total amount of isofenphos recovered from the air filters was divided by the total volume of air sample, multiplied by the respiration rate and hours worked per replicate to provide the amount of isofenphos in mg/replicate. The dermal gauze pad values were multiplied by the location area in $cm^2$ to provide the exposure in mg isofenphos per location. These values were summed to provide dermal gauze exposure values in mg/replicate. Handwash samples were calculated using the same calculations as dermal exposures, assuming an area of 410 $cm^2$.

Versar estimated exposure values as mg/lb ai handled as per EPA's request. Versar calculated both potential (based on exterior patches) and actual (based on interior patches) dermal exposures. The Registrant corrected all data for field fortification recoveries, including recoveries above 90%. For those values below the LOD, the Registrant used ½ the recovery corrected LOD value. Versar only corrected data for field fortification recoveries less <90% and reported non-detect values as ½ LOD.

Inhalation Exposure

Inhalation exposures were calculated by both the Registrant and Versar from the breathing-zone air concentrations determined from the amount of isofenphos found on the air-sampling filters and the volume of air sample. A moderate workrate respiratory rate of 0.029 $m^3$/min was assumed by the Registrant for the duration of the sampling period. Versar used the NAFTA recommended inhalation rate of 0.029 $m^3$/min for moderate activities. According to the Registrant's calculations, the geometric mean of the inhalation exposure was 0.0003 mg/lb ai with a geometric standard deviation of 3.7. Since no sample was collected for replicate 5, the Registrant used the geometric mean of all inhalation exposures as the value for replicate 5 in their calculations. Table 4 provides the Versar-calculated potential inhalation exposures. The average exposure was 0.0006 ± 0.0008 mg/lb ai handled.

Potential Dermal Exposure

Potential dermal exposure estimates were calculated by extrapolating values from exterior patches to the total surface area of the appropriate region. The Registrant did not report potential dermal exposures, although exterior dermal patches were analyzed and raw data were reported in the Study Report. Versar calculated potential dermal estimates for each region of the

body using the exterior patches (see Table 5). The total surface area of the exposed surfaces of the dermal patches was 24.63 $cm^2$. Versar used the default NAFTA surface areas to calculate the potential dermal exposure for each body region. Total potential dermal exposures ranged from 0.0095 to 1.2369 mg/lb ai handled. The primary body region contributors were the lower arm (0.1110 mg/lb ai handled) and the lower leg (0.0712 mg/lb ai handled). The overall average total potential dermal exposure was 0.3326 ± 0.3555 mg/lb ai handled.

Actual Dermal Exposure

Actual dermal exposure estimates were calculated by extrapolating patch values from interior patches to the total surface area of the appropriate region. The Registrant extrapolated these values using recommended surface area estimates found in the EPA Pesticide Registration Guidelines, Subdivision U, Applicator Exposure. The surface area of the exposed surfaces of the dermal patches was 24.63 $cm^2$. For actual dermal exposure to the head, the Registrant used the interior head patch value multiplied by a penetration factor of 0.13. This factor was calculated from the gauze dosimeter data by dividing the amount on an inner dosimeter by the amount on the adjacent outer dosimeter, in every case where both dosimeters had measurable amounts. The Registrant reported total dermal exposure as the sum of the values for covered skin, head and neck, and hands. The Registrant calculated hand exposures assuming an exposed area of 410 $cm^2$ and followed the same calculations as those used for dermal exposure. According to the Registrant's calculations, hand exposures ranged from 0.059 to 0.42 mg/lb ai applied, with an average hand exposure of 0.11 mg/lb ai applied. Versar's calculated hand exposures are reported in Table 6. These exposures ranged from 0.003 to 0.333 mg/lb ai handled. The overall average hand exposure was 0.033 ± 0.095 mg/lb ai handled.

The Registrant calculated a geometric mean total dermal exposure of 0.15 mg/lb ai applied. Versar calculated actual dermal estimates for each region of the body using the interior patches (except for the head) (see Table 7). Versar used the default NAFTA surface areas to calculate the actual dermal exposure for each body region. The actual dermal exposure estimates ranged from 0.0028 to 0.1053 mg/lb ai handled with an overall average actual dermal exposure of 0.0296 ± 0.0314 mg/lb ai handled. Total dermal exposure estimates included both actual dermal exposures and hand exposures and averaged 0.0597 ± 0.1001 mg/lb ai handled.

Total Exposure

Total exposure was calculated by taking the sum of all exposure routes (dermal-hands, dermal-body, and inhalation). The Registrant calculated a geometric mean total exposure of 0.15 mg/lb ai applied. Versar's calculated total exposure is presented in Table 8 and averaged 0.060 ± 0.101 mg/lb ai handled.

## III DISCUSSION

### A. LIMITATIONS OF THE STUDY:

The study met most of the Series 875.1100 and 875.1300 Guidelines. The major issues of concern were: (1) this study was performed at only one test site, (2) raw field data were corrected for all recoveries, even those greater than 90%, (3) concurrent laboratory fortification recoveries were not provided in the Study Report, (4) the limit of quantification was not provided for any media, only the limit of detection, (5) the analysis dates were not provided for any of the samples in this study in order to verify storage stability results, (6) individual field blank results were not provided in the Study Report, (7) there was only one field fortification level for air filter samples, (8) the Registrant used ½ the recovery corrected sample quantification limits for non-detect values, rather than ½ the method limit of detection for that media, (9) method validation recoveries were not provided for handwash samples, (10) information on the individuals who participated in this study was not provided, (11) the inhalation methodology was calibrated with an airflow of 1L/min instead of 2L/min, (12) the Registrant used the inhalation geometric mean for replicate 5 since no sample was collected, (13) the Registrant used values slightly different from the NAFTA recommended body region surface areas, and (14) the Registrant calculated face exposures from head exposures.

### B. CONCLUSIONS:

Dermal and inhalation exposures were assessed during the planting of treated canola seed. The workers performed both loading of the treated seed into seed hoppers and planting of the seed. Table 8 provides a summary of the total exposure to isofenphos during loading and planting of treated seed, as calculated by Versar. Versar's calculated average total exposure was 0.060 ± 0.101 mg/lb-ai handled. The geometric mean total exposure, as calculated by the Registrant, to isofenphos during planting of treated canola seed was 0.15 mg/lb ai applied. The study author also reported total exposure in mg/replicate and assumed that a worker is able to complete three replicates per day. The study author estimated an average daily exposure of 1.9 mg, but noted that a worker would probably not routinely work what is equivalent to three replicates per day during the planting season so that actual daily exposure would likely be less than 1.9 mg/day.

Table 4. Potential Inhalation (mg/lb ai handled) Based on Residue Levels Found on Air Filters.

| Replicate | Residue ( $\mu$g/sample) | Corrected Value ($\mu$g/sample)[b] | Replicate length (min) | Volume of air sampled (L) | Concentration (mg/m$^3$)[c] | lb ai handled | Respiration Rate (m$^3$/min) | Inhalation exposure (mg/lb ai handled)[d] |
|---|---|---|---|---|---|---|---|---|
| 1 | 0.0664 | 0.0754 | 164 | 164 | 0.00046 | 1.92 | 0.029 | 0.00114 |
| 2 | 0.1530 | 0.1737 | 135 | 135 | 0.00129 | 2.88 | 0.029 | 0.00175 |
| 3 | 0.0339 | 0.0385 | 260 | 286 | 0.00013 | 5.95 | 0.029 | 0.00017 |
| 4 | 0.0289 | 0.0328 | 185 | 203.5 | 0.00016 | 4.32 | 0.029 | 0.00020 |
| 6 | 0.0219 | 0.0249 | 185 | 203.5 | 0.00012 | 3.60 | 0.029 | 0.00018 |
| 8 | a | 0.0050 | 110 | 107.8 | 0.00002 | 4.32 | 0.029 | 0.00002 |
| 9 | 0.2260 | 0.1793 | 285 | 107.8 | 0.00166 | 5.76 | 0.029 | 0.00239 |
| 11 | 0.0608 | 0.0482 | 217 | 238.7 | 0.00020 | 2.94 | 0.029 | 0.00043 |
| 13 | a | 0.0050 | 172 | 189.2 | 0.00001 | 4.62 | 0.029 | 0.00001 |
| 14 | a | 0.0050 | 155 | 170.5 | 0.00001 | 3.96 | 0.029 | 0.00002 |
| 15 | 0.0426 | 0.0454 | 277 | 304.7 | 0.00015 | 6.24 | 0.029 | 0.00019 |
| 16 | 0.0460 | 0.0490 | 188 | 206.8 | 0.00024 | 5.46 | 0.029 | 0.00024 |
| **Mean** | | | | | | | | 0.0006 |
| **Geometric Mean** | | | | | | | | 0.0002 |
| **Standard Deviation** | | | | | | | | 0.0008 |
| **Coefficient of Variance (%)** | | | | | | | | 138.58 |

a Residue was not detected. Therefore, ½ the LOD (0.005 $\mu$g/sample) was used.
b Corrected for average field fortification recovery (88.1%)
c Concentration (mg/m$^3$) = (Residue ($\mu$g/sample) x 0.001)/(sample volume (L) x m$^3$/1000L)
d Exposure (mg/lb ai handled) = [(Concentration (mg/m$^3$) x Respiration rate (m$^3$/min) x replicate length (min)]/lb ai handled

Table 5. Potential Dermal Exposure (mg/lb ai handled) Based on Exterior Patches

| Replicate | Residues ($u$g/cm$^2$)[a] | | | | | | | | Body Region Exposure (mg/lb ai handled)[c] | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Head | Back | Chest | Upper Arm | Lower Arm | Upper Leg | Lower Leg | lb ai applied | Head (1300 cm$^2$) | Back (3550 cm$^2$) | Chest (3550 cm$^2$) | Upper Arm (2910 cm$^2$) | Lower Arm (1210 cm$^2$) | Upper Leg (382 cm$^2$) | Lower Leg (2380 cm$^2$) | Total |
| 1 | 0.008 | 0.007 | 0.016 | 0.026 | 0.333 | 0.510 | 0.069 | 1.92 | 0.0054 | 0.1306 | 0.0302 | 0.0388 | 0.2096 | 0.1014 | 0.0856 | 0.6015 |
| 2 | 0.041 | 0.007 | 0.229 | 0.107 | 1.473 | 0.327 | 0.096 | 2.88 | 0.0185 | 0.0856 | 0.2828 | 0.1085 | 0.6188 | 0.0434 | 0.0794 | 1.2369 |
| 3 | 0.001[b] | 0.001[b] | 0.014 | 0.017 | 0.140 | 0.353 | 0.093 | 5.95 | 0 | 0.005 | 0.009 | 0.0083 | 0.0284 | 0.0227 | 0.0373 | 0.1101 |
| 4 | 0.001[b] | 0.001[b] | 0.001[b] | 0.011 | 0.029 | 0.294 | 0.037 | 4.32 | 0 | 0.006 | 0 | 0.0077 | 0.0083 | 0.026 | 0.0201 | 0.0693 |
| 5 | 0.008 | 0.006 | 0.147 | 0.003 | 0.190 | 0.308 | 0.519 | 4.32 | 0.0025 | 0.05 | 0.1211 | 0.002 | 0.0531 | 0.0272 | 0.2861 | 0.5421 |
| 6 | 0.020 | 0.001[b] | 0.097 | 0.013 | 0.043 | 0.179 | 0.161 | 3.6 | 0.0071 | 0.008 | 0.0961 | 0.0103 | 0.0143 | 0.019 | 0.1066 | 0.2609 |
| 8 | 0.001[b] | 0.001[b] | 0.001[b] | 0.001[b] | 0.007 | 0.001[b] | 0.001[b] | 4.32 | 0 | 0.006 | 0 | 0.001 | 0.002 | 0 | 0 | 0.0103 |
| 9 | 0.050 | 0.024 | 0.217 | 0.074 | 0.353 | 0.522 | 0.036 | 5.76 | 0.0113 | 0.1491 | 0.1339 | 0.0373 | 0.0742 | 0.0346 | 0.0148 | 0.4552 |
| 11 | 0.010 | 0.001[b] | 0.001[b] | 0.007 | 0.038 | 0.073 | 0.035 | 2.94 | 0.0044 | 0.009 | 0 | 0.0072 | 0.0158 | 0.01 | 0.028 | 0.0751 |
| 13 | 0.008 | 0.008 | 0.073 | 0.029 | 1.469 | 0.327 | 0.183 | 4.62 | 0.0021 | 0.0608 | 0.0565 | 0.0184 | 0.3847 | 0.027 | 0.0941 | 0.6437 |
| 14 | 0.001[b] | 0.001[b] | 0.001[b] | 0.001[b] | 0.001 | 0.004 | 0.001[b] | 3.96 | 0 | 0.007 | 0 | 0.001 | 0 | 0 | 0 | 0.0095 |
| 15 | 0.008 | 0.006 | 0.026 | 0.047 | 0.143 | 0.184 | 0.299 | 6.24 | 0.0017 | 0.0321 | 0.0133 | 0.022 | 0.0278 | 0.0113 | 0.1139 | 0.2222 |
| 16 | 0.001[b] | 0.001[b] | 0.014 | 0.001[b] | 0.024 | 0.127 | 0.134 | 5.46 | 0 | 0.005 | 0.009 | 0 | 0.0053 | 0.009 | 0.0585 | 0.0877 |
| **Average** | 0.012 | 0.005 | 0.064 | 0.026 | 0.326 | 0.247 | 0.128 | 4.33 | 0.0042 | 0.0427 | 0.0581 | 0.0202 | 0.111 | 0.0255 | 0.0712 | 0.3326 |
| **Standard Deviation** | | | | | | | | | | | | | | | | 0.3555 |

a Residue ($\mu$g/cm$^2$) = Residue ($\mu$g/sample)/Patch surface area (24.63 cm$^2$)
b Residue was not detected. Therefore, ½ the LOD (0.038 $\mu$g/sample) was used.
c Body Region Exposure (mg/lb-ai)= (Exposure ($u$g/cm$^2$) x Body Region (cm$^2$)/lb ai applied) x 0.001

Table 6. Summary of Hand Exposure (mg/lb ai handled) based on Hand Washes

| Replicate | Residue - both hands ($\mu$g/sample ) | lb ai handled | Hand exposure ($\mu$g /lb ai handled) | Hand exposure (mg/lb ai handled) |
|---|---|---|---|---|
| 1 | 0.33333333333 | 1.92 | 10.4 | 0.010 |
| 2 | 0.33333333333 | 2.88 | 6.9 | 0.007 |
| 3 | 0.33333333333 | 5.95 | 3.4 | 0.003 |
| 4 | 0.33333333333 | 4.32 | 4.6 | 0.005 |
| 5 | 0.33333333333 | 4.32 | 4.6 | 0.005 |
| 6 | 0.33333333333 | 3.60 | 5.6 | 0.006 |
| 9 | 1920 | 5.76 | 333.3 | 0.333 |
| 11 | 0.33333333333 | 2.94 | 6.8 | 0.007 |
| 13 | 0.33333333333 | 4.62 | 4.3 | 0.004 |
| 14 | 0.33333333333 | 3.94 | 5.1 | 0.005 |
| 15 | 0.33333333333 | 6.24 | 3.2 | 0.003 |
| 16 | 0.33333333333 | 5.46 | 3.7 | 0.004 |
| **Mean** | | | | **0.033** |
| **Geometric Mean** | | | | **0.007** |
| **Standard Deviation** | | | | **0.095** |
| **Coefficient of Variance (%)** | | | | **289.98** |

a Residue value not detected. Therefore, ½ the LOD (40 $\mu$g/sample) was used.

Table 7. Actual Dermal Exposure (mg/lb ai handled) Based on Interior Patches (except for Head)

| Replicate | Residues ($u$g/cm$^2$)[a] | | | | | | | | | Body Region Exposure (mg/lb ai handled)[c] | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Neck[b] | Head | Back | Chest | Upper Arm | Lower Arm | Upper Leg | Lower Leg | lb ai applied | Neck[b] | Head (1300 cm$^2$) | Back (3550 cm$^2$) | Chest (3550 cm$^2$) | Upper Arm (2910 cm$^2$) | Lower Arm (1210 cm$^2$) | Upper Leg (382 cm$^2$) | Lower Leg (2380 cm$^2$) | Total |
| 1 | 0.023 | 0.008 | 0.001 | 0.001 | 0.001 | 0.081 | 0.033 | 0.004 | 1.92 | 0.002 | 0.005 | 0 | 0 | 0 | 0.05 | 0.007 | 0.004 | 0.073 |
| 2 | 0.236 | 0.041 | 0.001 | 0.022 | 0.006 | 0.076 | 0.036 | 0.004 | 2.88 | 0.0122 | 0.0185 | 0 | 0.03 | 0 | 0.03 | 0.005 | 0.003 | 0.1053 |
| 3 | 0.015 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.016 | 0.001 | 5.95 | 0 | 0 | 0 | 0 | 0 | 0 | 0.001 | 0 | 0 |
| 4 | 0.002 | 0.001 | 0.001 | 0.001 | 0.001 | 0.006 | 0.013 | 0.001 | 4.32 | 0 | 0 | 0 | 0 | 0 | 0 | 0.001 | 0 | 0.01 |
| 5 | 0.154 | 0.008 | 0.001 | 0.001 | 0.001 | 0.017 | 0.024 | 0.015 | 4.32 | 0.005 | 0.003 | 0 | 0 | 0 | 0 | 0.002 | 0.008 | 0.025 |
| 6 | 0.098 | 0.020 | 0.001 | 0.001 | 0.001 | 0.001 | 0.004 | 0.003 | 3.6 | 0.004 | 0.007 | 0 | 0 | 0 | 0 | 0 | 0.002 | 0.016 |
| 8 | 0.0015 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 4.32 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9 | 0.241 | 0.030 | 0.001 | 0.014 | 0.003 | 0.020 | 0.061 | 0.012 | 5.76 | 0.006 | 0.0113 | 0 | 0 | 0 | 0 | 0.004 | 0.005 | 0.041 |
| 11 | 0.0015 | 0.010 | 0.001 | 0.001 | 0.001 | 0.004 | 0.010 | 0.001 | 2.94 | 0 | 0.004 | 0 | 0 | 0 | 0 | 0.001 | 0 | 0.011 |
| 13 | 0.081 | 0.008 | 0.016 | 0.003 | 0.016 | 0.030 | 0.059 | 0.029 | 4.62 | 0.003 | 0.002 | 0.01 | 0 | 0.01 | 0 | 0.005 | 0.0152 | 0.058 |
| 14 | 0.0015 | 0.001 | 0.005 | 0.001 | 0.001 | 0.001 | 0.010 | 0.009 | 3.96 | 0 | 0 | 0 | 0 | 0 | 0 | 0.001 | 0.005 | 0.012 |
| 15 | 0.0291 | 0.008 | 0.001 | 0.007 | 0.001 | 0.041 | 0.023 | 0.009 | 6.24 | 0 | 0.002 | 0 | 0 | 0 | 0 | 0.001 | 0.003 | 0.02 |
| 16 | 0.0152 | 0.001 | 0.001 | 0.001 | 0.008 | 0.003 | 0.011 | 0.010 | 5.46 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.004 | 0.012 |
| **Average** | 0.069 | 0.012 | 0.002 | 0.004 | 0.003 | 0.022 | 0.023 | 0.008 | 4.33 | 0.003 | 0.004 | 0 | 0 | 0 | 0 | 0.002 | 0.004 | 0.03 |
| **Standard Deviation** | | | | | | | | | | | | | | | | | | 0.031 |

a Residue ($\mu$g/cm$^2$) = Residue ($\mu$g/sample)/Patch surface area (24.63 cm$^2$)
b Sum of the calculations for both front and back neck (Areas: 150 and 110 cm$^2$, respectively)
c Body Region Exposure (mg/lb ai handled)= (Exposure ($u$g/cm$^2$) x Body Region (cm$^2$)/lb ai applied) x 0.001

Table 8. Total Exposure (mg/lb ai handled)

| Replicate | Exposure (mg/lb ai handled) | | | | |
|---|---|---|---|---|---|
| | Dermal-body | Dermal-hands | Dermal-Total | Inhalation | Inhalation + Dermal Total |
| 1 | 0.0731 | 0.0104 | 0.0835 | 0.0011 | 0.085 |
| 2 | 0.1053 | 0.0069 | 0.1122 | 0.0018 | 0.114 |
| 3 | 0.0033 | 0.0034 | 0.0067 | 0.0002 | 0.007 |
| 4 | 0.0053 | 0.0046 | 0.01 | 0.0002 | 0.01 |
| 5 | 0.0249 | 0.0046 | 0.0295 | | 0.029 |
| 6 | 0.016 | 0.0056 | 0.0216 | 0.0002 | 0.022 |
| 8 | 0.0028 | | 0.0028 | 0.00002 | 0.003 |
| 9 | 0.0411 | 0.3333 | 0.3745 | 0.0024 | 0.377 |
| 11 | 0.0108 | 0.0068 | 0.0176 | 0.0004 | 0.018 |
| 13 | 0.058 | 0.0043 | 0.0623 | 0.00001 | 0.062 |
| 14 | 0.0124 | 0.0051 | 0.0174 | 0.00002 | 0.017 |
| 15 | 0.0199 | 0.0032 | 0.0231 | 0.0002 | 0.023 |
| 16 | 0.0117 | 0.0037 | 0.0153 | 0.0002 | 0.016 |
| **Average** | 0.0296 | 0.0327 | 0.0597 | 0.0006 | 0.06 |
| **Standard Deviation** | | | | | 0.101 |

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Name:
Evaluator
Occupational Exposure Assessment Section

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Date

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Name:
Peer Reviewer
Occupational Exposure Assessment Section

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Date

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Name:
Head,
Occupational Exposure Assessment Section

_____
Date

**Compliance Checklist**

Compliance with OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A: Guidelines, 875.1300 (inhalation), and 875.1100 (dermal) is critical. The itemized checklist below describes compliance with the major technical aspects of OPPTS 875.1300, and 875.1100.

875.1300

– *Investigators should submit protocols for review purposes prior to the inception of the study.* This criterion was probably met.

3) *Expected deviations from GLPs should be presented concurrently with any protocol deviations and their potential study impacts.* The study sponsor stated that GLP's did not apply to this study.

4) *The test substance should be a typical end use product of the active ingredient.* This criterion was met.

5) *The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate may be more appropriate in certain cases.* It is uncertain whether this criterion was met. A product label was not provided in the study and the label obtained by Versar did not provide a maximum application rate.

6) *Selected sites and seasonal timing of monitoring should be appropriate to the activity.* It is uncertain whether these criteria were met. The study site was located in Canada and the study occurred during the month of May.

7) *A sufficient number of replicates should be generated to address the exposure issues associated with the population of interest. For outdoor exposure monitoring, each study should include a minimum of 15 individuals (replicates) per activity.* This criterion was met. Four individuals participated in this study, for a total of 16 replicates.

8) *The quantity of active ingredient handled and the duration of the monitoring period should be reported for each replicate*. This criterion was met.

9) *Test subjects should be regular workers, volunteers trained in the work activities required, or typical homeowners*. This criterion was met.

10) *The monitored activity should be representative of a typical working day for the specific task in order to capture all related exposure activities.* This criterion was met.

11) *When both dermal and inhalation monitoring are required, field studies designed to measure exposure by both routes on the same subjects may be used*. This criterion was met.

12) *The analytical procedure must be capable of measuring exposure to 1 µg/hr (or less, if the toxicity of the material under study warrants greater sensitivity).* This criterion was met.

13) *A trapping efficiency test for the monitoring media chosen must be documented.* This criterion was not met. Trapping efficiency tests were not documented for any of the media used in this study.

14) *Air samples should also be tested for breakthrough to ensure that collected material is not lost from the medium during sampling. It is recommended that at least one test be carried out where the initial trap contains 10X the highest amount of residue expected in the field.* This criterion was not met. There was no mention of any breakthrough tests being run on the air filters used in the study.

15) *The extraction efficiency of laboratory fortified controls is considered acceptable if the lower limit of the 95% confidence interval is greater than 75%, unless otherwise specified by the Agency. At a minimum, seven determinations should be made at each fortification level to calculate the mean and standard deviation for recovery. Total recovery from field-fortified samples must be greater than 50% for the study.* These criteria were partially met. The number of laboratory fortified controls and types of laboratory controls were not provided in the Study Report.

Field fortification results were provided and all were greater than 50%.

16) *If trapping media or extracts from field samples are to be stored after exposure, a stability test of the compound of interest must be documented. Media must be stored under the same conditions as field samples. Storage stability samples should be extracted and analyzed immediately before and at appropriate periods during storage. The time periods for storage should be chosen so that the longest corresponds to the longest projected storage period for field samples.* This criterion was met. A storage stability test was conducted. The Registrant, however, did not provide the actual dates of analysis.

17) *A personal monitoring pump capable of producing an airflow of at least 2 L/min. should be used and its batteries should be capable of sustaining maximum airflow for at least 4 hours without recharging. Airflow should be measured at the beginning and end of the exposure period.* This criterion was probably not met. Personal monitoring pumps were calibrated to 1 L/min and it was not reported if airflow was measured at the beginning and/or end of the exposure period.

18) *Appropriate air sampling media should be selected. The medium should entrap a high percentage of the chemical passing through it, and it should allow the elution of a high percentage of the entrapped chemical for analysis.* This criterion was met. The study utilized personal air samplers containing air filters and absorption tubes.

19) *If exposed media are to be stored prior to extraction, storage envelopes made from heavy filter paper may be used. The envelope must be checked for material that will interfere with analysis. Unwaxed sandwich bags should be used to contain the filter paper envelopes to help protect against contamination.* This criterion was probably met. The Registrant states that after collection of the fiberglass filters, the air filter cassettes were removed, capped, and place in Whirl-Pak bags.

20) *Personal monitors should be arranged with the intake tube positioned downward, as near as possible to the nose level of the subject.* This criterion was met. The cassette containing the air filter was attached to the worker's lapel.

21) *Field calibration of personal monitors should be performed at the beginning and end of the exposure period.* It is uncertain whether this criterion was met. There was no mention of calibration procedures in the Study Report.

22) *Field fortification samples and blanks should be analyzed for correction of residue losses occurring during the exposure period. Fortified samples and blanks should be fortified at the expected residue level of the actual field samples. Fortified blanks should be exposed to the same weather conditions.* These criteria were met. The Registrant mentioned that both field fortified samples and field blanks were collected.

23) *Data should be corrected if any appropriate field fortified, laboratory fortified or storage stability recovery is less than 90 percent.* This criterion was met. The Registrant corrected all data for field recoveries, even those greater than 90%.

24) *Respirator pads should be removed using clean tweezers and placed in protective white crepe filter paper envelopes inside sandwich bags. The pads should be stored in a chest containing ice until they are returned to the laboratory, where they should be stored in a freezer prior to extraction.* This criterion was not applicable to this study.

25) *Field data should be documented, including chemical information, area description, weather conditions, application data, equipment information, information on work activity monitored, sample numbers, exposure time, and any other observations.* These criteria were partially met. Brief descriptions of the test product used, the work activities being monitored, the planting equipment used, the application rate, the location of the study, and weather conditions were provided in the Study Report. However, no information regarding the individuals used in the study was provided.

26) *Analysis methods should be documented and appropriate.* This criterion was met.

27) *A sample history sheet must be prepared by the laboratory upon receipt of samples.* This criterion was not met.

875.1100

28) *Investigators should submit protocols for review purposes prior to the inception of the study.* This criterion was probably met.

29) *Expected deviations from GLPs should be presented concurrently with any protocol deviations and their potential study impacts.* The study sponsor stated that GLP's did not apply to this study.

30) *The test substance should be a typical end use product of the active ingredient.* This criterion was met.

31) *The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate may be more appropriate in certain cases.* It is uncertain whether this criterion was met. A product label was not provided in the study and the label obtained by Versar did not provide a maximum application rate.

32) *Selected sites and seasonal timing of monitoring should be appropriate to the activity.* It is uncertain whether these criteria were met. The study site was located in Canada and the study occurred during the month of May.

33) *A sufficient number of replicates should be generated to address the exposure issues associated with the population of interest. For outdoor exposure monitoring, each study should include a minimum of 15 individuals (replicates) per activity.* This criterion was met. Four individuals participated in this study, for a total of 16 replicates.

34) *The quantity of active ingredient handled and the duration of the monitoring period should be reported for each replicate*. This criterion was met.

35) *Test subjects should be regular workers, volunteers trained in the work activities required, or typical homeowners*. This criterion was met.

36) *Any protective clothing worn by the test subjects should be identified and should be consistent with the product label.* This criterion was met. The protective clothing worn by the test subjects was identified and was consistent with the product label obtained by Versar.

37) *The monitored activity should be representative of a typical working day for the specific task in order to capture all related exposure activities.* This criterion was met.

38) *Dermal exposure pads used for estimating dermal exposure to sprays should be constructed from paper-making pulp or similar material (i.e., alpha-cellulose), approximately 1 mm thick, that will absorb a considerable amount of spray without disintegrating. The alpha-cellulose material should not typically require preextraction to remove substances that interfere with residue analysis. This should be determined prior to using the pads in exposure tests* .This criterion is not applicable to this study.

39) *Dermal exposure pads used for estimating dermal exposure to dust formulations, dried residues, and to dust from granular formulation should be constructed from layers of surgical gauze. The pad should be bound so that an area of gauze at least 2.5 inch square is left exposed. The gauze must be checked for material that would interfere with analysis and be preextracted if necessary.* These criteria were partially met. The exposure pads were constructed from a surgical sponge and had a circular opening 5.6 cm (2.2 in) in diameter. It was not stated whether the gauze was checked for material that would interfere with analysis.

40) *A complete set of pads for each exposure period should consist of 10 to 12 pads. If the determination of actual penetration of work clothing is desired in the field study, additional pads can be attached under the worker's outer garments. Pads should be attached under both upper and lower outer garments, particularly in regions expected to receive maximum exposure. Pads under clothing should be near, but not covered by, pads on the outside of the clothing*. This criterion was met.

41) *If exposed pads are to be stored prior to extraction, storage envelopes made from heavy filter paper may be used. The envelope must be checked for material that will interfere with analysis. Unwaxed sandwich bags should be used to contain the filter paper envelopes to help protect against contamination.* This criterion was not met. Gauze pads were stored in 1-ounce glass bottles capped with poly-seal screw caps and stored on dry ice.

42) *Hand rinses should be performed during preliminary studies to ensure that interferences are not present. Plastic bags designed to contain 0.5 gal and strong enough to withstand vigorous shaking (i.e., at least 1 mil inch thickness) should be used. During preliminary studies, plastic bags must be shaken with the solvent to be used in the study to ensure that material which may interfere with analysis is not present.* It is unknown if this criterion was met. The study author made no mention of preliminary hand rinse studies.

*43) The analytical procedure must be capable of quantitative detection of residues on exposure pads at a level of 1 ug/cm$^2$ (or less, if the dermal toxicity of the material under study warrants greater sensitivity).* It is unknown if this criterion was met. The limit of quantification was not provided in the study. The limit of detection for exposure pads was reported as 38 ng/sample.

44) *The extraction efficiency of laboratory fortified controls is considered acceptable if the lower limit of the 95% confidence interval is greater than 75%, unless otherwise specified by the Agency. At a minimum, seven determinations should be made at each fortification level to calculate the mean and standard deviation for recovery. Total recovery from field-fortified samples must be greater than 50% for the study.* These criteria were partially met. The number of laboratory fortified controls and types of laboratory controls were not provided in the Study Report. Field fortification recovery results were provided and all were greater than 50%.

*45) If the stability of the material of interest is unknown, or if the material is subject to degradation, the investigator must undertake and document a study to ascertain loss of residues while the pads are worn. It is recommended that collection devices be fortified with the same levels expected to occur during the field studies. The dosimeters should be exposed to similar weather conditions and for the same time period as those expected during field studies.* These criteria were met. A storage stability test was conducted. The Registrant, however, did not provide the actual dates of analysis.

*46) Data should be corrected if any appropriate field fortified, laboratory fortified or storage stability recovery is less than 90 percent.* This criterion was met. The Registrant corrected all raw residue data for field recoveries.

47) *Field data should be documented, including chemical information, area description, weather conditions, application data, equipment information, information on work activity monitored, sample numbers, exposure time, and any other observations.* These criteria were partially met. Brief descriptions of the test produce used, the work activities being monitored, the planting equipment used, the application rate, the location of the study, and the weather conditions were provided in the Study Report. However, no information regarding the individuals used in the study was provided.

48) *A sample history sheet must be prepared by the laboratory upon receipt of samples.* This criterion was not met.

APPENDIX B

Comparison of Application Rates of Lindane Among Registered Crops

| Group | Crop | Ounce ai/cwt | Max Seed Lb ai/acre | Max Seed cwt/acre | Max Ounce ai/acre | Max Pound ai/acre |
|---|---|---|---|---|---|---|
| Root & Tuber | Radish | 0.53 | 20 | 0.2 | 0.106 | 0.0066 |
| | | | | | | |
| Leafy Veggies | Celery | 1.31 | 2 | 0.02 | 0.0262 | 0.0016 |
| | Lettuce | 1.31 | 3 | 0.03 | 0.0393 | 0.0025 |
| | Swiss | 1.31 | 8 | 0.08 | 0.1048 | 0.0066 |
| | Spinach | 1.31 | 15 | 0.15 | 0.1965 | 0.0123 |
| | | | | | | |
| Cereal Grains | Corn | 2 | 18 | 0.18 | 0.36 | 0.0225 |
| | Barley | 0.5 | 96 | 0.96 | 0.48 | 0.0300 |
| | Oats | 0.6 | 128 | 1.28 | 0.768 | 0.0480 |
| | Rye | 0.5 | 112 | 1.12 | 0.56 | 0.0350 |
| | Soughum | 1.13 | 75 | 0.75 | 0.8475 | 0.0530 |
| | Wheat | 0.68 | 120 | 1.2 | 0.816 | 0.0510 |
| | | | | | | |
| Misc. | Canola | 23.3 | 4 | 0.04 | 0.932 | 0.0583 |
| | | | | | | |
| Brassica | Broccoli | 1.91 | 1.5 | 0.015 | 0.02865 | 0.0018 |
| | Brussels | 1.91 | 1.5 | 0.015 | 0.02865 | 0.0018 |
| | Cabbage | 1.91 | 1.5 | 0.015 | 0.02865 | 0.0018 |
| | Cauli | 1.91 | 1.5 | 0.015 | 0.02865 | 0.0018 |
| | Collards | 1.91 | 4 | 0.04 | 0.0764 | 0.0048 |
| | Kale | 1.91 | 4 | 0.04 | 0.0764 | 0.0048 |
| | Kohlrabi | 1.91 | 5 | 0.05 | 0.0955 | 0.0060 |
| | Mustard | 1.91 | 5 | 0.05 | 0.0955 | 0.0060 |

Source for Maximum Lb Seed per Acre: Martin, J. H., W. H. Leonard, and D. L. Stamp, “Principles of Field Crop Production, Third Edition:, Macmillan Publishing Co., Inc., 1976.